

REMARKS

Re-consideration of the above-identified application in view of the following remarks is respectfully requested.

Claims 1-4, 5 and 7-15 are in this case. Claims 1-4 were withdrawn under a restriction requirement as drawn to a non-elected invention. Claims 5 and 7-15 have been rejected. Claim 5 has now been amended. Claim 15 has now been cancelled.

35 U.S.C. §112, First Paragraph, Rejections

The Examiner has rejected claims 5-15 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner states that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Examiner's rejections are respectfully traversed. Claim 5 has now been amended. Claim 6 was previously cancelled. Claim 15 has now been cancelled.

In particular, the Examiner states that support for the phrase "at physiological conditions" cannot be found in the specification or claims as originally filed.

Claim 5 has now been amended to include the limitation that the complex is stable "at a temperature not exceeding 60 °C" which defines the thermal stability of the protein instead of the phrase "physiological conditions". Support for this claim language can be found in Page 54 lines 18-19 and Page 55 lines 1-5, in which the thermal stability of the MHC class I-antigenic peptide complex was shown by incubating the MHC class I-G9-209-2M complex under extreme temperatures (*i.e.*, up to 80 °C). The functional and thermally stable MHC class I-antigenic peptide complex of the present invention retained its specific pattern of secondary structure up to a temperature of 60 °C as was revealed by the melting curve of the G9-209-containing MHC-peptide complex using circular dichroism (CD) spectroscopy assay.

In view of the above arguments and amendments, Applicant believes to have overcome the 35 U.S.C. §112, first paragraph rejection.

35 U.S.C. §112, Second Paragraph, Rejections

The Examiner has rejected claim 5 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, the Examiner points out that claims 5 and 15 are ambiguous and unclear in the recitation of “physiological conditions”. Claim 5 has now been amended. Claim 15 has now been cancelled.

As mentioned hereinabove, Applicant has elected to remove the phrase “physiological conditions” from the claims and to place the limitation that the complex is stable “at a temperature not exceeding 60 °C”

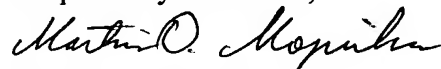
The Examiner further points out that claim 5 is ambiguous and unclear in the recitation of “refolding” in step (c) and that there is nothing in the procedure that would suggest that the peptide has been unfolded. The Examiner’s rejection is respectfully traversed.

Applicant wishes to point out that the term “refolding” refers to the single chain MHC class I polypeptide and not the peptide. In addition, Applicant wishes to further point out that it is an inherent characteristic of the MHC class I polypeptide to fold improperly when expressed in bacteria and therefore to form protein aggregates in insoluble inclusion bodies. As explained in Example 1 of the instant application (see page 46 lines 4-19), in order to form a complex which comprises the single chain MHC class I polypeptide and the antigenic peptide, the inclusion bodies are refolded in a redox-shuffling buffer in the presence of the antigenic peptide.

In view of the above arguments and claim amendments, Applicant believes to have overcome the 35 U.S.C. §112, second paragraph rejection.

In view of the above amendments and remarks it is respectfully submitted that claims 5 and 7-14 are now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,



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